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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,109	01/26/2001	Allan S. Lau	4099-0003.31	8965

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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/22/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/772,109

Applicant(s)

LAU ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-12 and 25-40, drawn to a human cell line that is able to produce one or more cytokines, classified in class 435, subclass 325.
2. Claims 13-24, drawn to a method of improving the production of interferon-alpha from a human cell line, classified in class 424, subclass 85.4.
3. Claims 13 and 19, drawn to a method of improving the production of interferon-beta from a human cell line, classified in class 424, subclass 85.4.
4. Claims 13 and 19, drawn to a method of improving the production of interferon-gamma from a human cell line, classified in class 424, subclass 85.4.
5. Claims 13 and 19, drawn to a method of improving the production of granulocyte macrophage stimulating factor from a human cell line, classified in class 424, subclass 85.1.
6. Claims 13 and 19, drawn to a method of improving the production of granulocyte colony stimulating factor from a human cell line, classified in class 424, subclass 85.1.
7. Claims 13 and 19, drawn to a method of improving the production of interleukin-2 from a human cell line, classified in class 424, subclass 85.2.
8. Claims 13 and 19, drawn to a method of improving the production of interleukin-3 from a human cell line, classified in class 424, subclass 85.2.
9. Claims 13 and 19, drawn to a method of improving the production of interleukin-7 from a human cell line, classified in class 424, subclass 85.2.

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10. Claims 13 and 19, drawn to a method of improving the production of interleukin-8 from a human cell line, classified in class 424, subclass 85.2.
11. Claims 13 and 19, drawn to a method of improving the production of interleukin-10 from a human cell line, classified in class 424, subclass 85.2.
12. Claims 13 and 19, drawn to a method of improving the production of interleukin-12 from a human cell line, classified in class 424, subclass 85.2.

The inventions are distinct, each from the other because of the following reasons:

Group 1 is drawn to a composition and is distinct from groups 2-12 which are drawn to methods. Group 1 is drawn to a cell line, which is capable of producing one or more cytokines.

Groups 2-12 are drawn to methods and each is distinct from the other by utilizing different starting materials. Because the DNA coding for the cytokines is different for each of groups 2-12, their structure differs, therefore the final product produced from each group is different.

Claim 13 link(s) inventions 2-12. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 13. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory

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double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their divergent subject matter, different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Additionally, Groups 1 and 2 contain claims directed to the following patentably distinct species of the claimed invention:

Priming compound:

- (a) phorbol myristate acetate ✓
- (b) interferon -beta

These species are distinct because they are structurally unrelated compounds, therefore they are not obvious in view of each other.

Inducing agent:

- (c) Sendai virus
- (d) encephalomyocarditis virus
- (e) Herpes Simplex virus
- (f) poly I:C ✓
- (g) poly I:rC
- (h) heparin
- (i) dextran sulfate
- (j) cylohexamide
- (k) actinomycin D
- (l) sodium butyrate
- (m) calcium ionophore
- (n) chondroitin sulfate
- (o) poly I:C, cylohexamide and actinomycin D

These species are distinct because they represent structurally unrelated compounds, therefore they are not obvious in view of each other.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for the priming agent and the inducing agent for prosecution on the merits to which the claims shall be restricted if no generic claim (claims 1 and 13) is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Ulrike Winkler, Ph.D.


JEFFREY STUCKER
PRIMARY EXAMINER